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510(k) Summary

1 Submitter Information

A.	Company Name:	Synovis Orthopedic and Woundcare, Inc.
B.	Company Address:	6 Jenner, Suite 150 Irvine, CA 92618
C.	Company Phone:	(949) 502-3240
D.	Company Facsimile:	(949) 502-3241
E.	Contact Person:	Amy Boucly Manager, Regulatory Affairs/Quality Assurance
F.	Date:	06/25/12

2 Device Identification

A.	Device Trade Name:	OrthADAPT® Bioimplant
B.	Common Name:	Surgical Mesh
C.	Classification Name(s):	Surgical Mesh
D.	Classification Regulation:	21 CFR 878.3300
E.	Device Class:	Class II
F.	Device Code(s):	OWY, FTM, OXE, OXB
G.	Advisory Panel:	General and Plastic Surgery

3 Identification of Predicate Devices

The OrthADAPT® Bioimplant is substantially equivalent to the OrthADAPT® Bioimplant (Surgical Mesh) manufactured by Synovis Orthopedic and Woundcare, Inc. and cleared for commercial distribution under 510(k) K043388.

4 Device Description

The OrthADAPT Bioimplant is a decellularized, equine pericardium. The OrthADAPT Bioimplant has been crosslinked and exposed to a liquid chemical sterilant. The product has passed the USP sterility test and satisfies FDA requirements for LAL endotoxin limit for a medical device. The product must be rinsed prior to use.

5 Indications for Use

The OrthADAPT Bioimplant (Surgical Mesh) is intended to be used for implantation to reinforce soft tissue including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement, and other reconstructive procedures.

The device is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

OrthADAPT is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

OrthADAPT is intended for one-time use only.

6 Substantial Equivalence

Supplier qualification activities, receiving controls, and design verification testing demonstrate that the modified OrthADAPT Bioimplant device is equivalent to the predicate device in terms of design, performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pegasus Biologics, Incorporated
% Ms. Pamela Misajon
Vice President, Regulatory Affairs, Clinical Affairs
6 Jenner, Suite 150
Irvine, California 92618

Re: K071065
Trade/Device Name: OrthADAPT® Bioimplant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXB, OXE, OWY
Dated: April 10, 2007
Received: April 18, 2007

AUG 29 2012

Dear Ms. Misajon:

This letter corrects our substantially equivalent letter of May 4, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

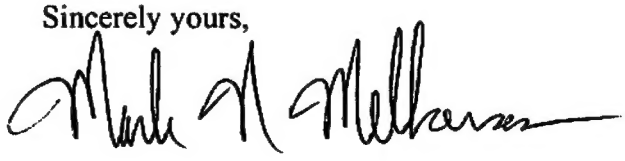
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071065

Device Name: OrthADAPT® Bioimplant

Indications For Use:

The OrthADAPT® Bioimplant (Surgical Mesh) is intended to be used for implantation to reinforce soft tissue including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement, and other reconstructive procedures.

The device is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

OrthADAPT® is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

OrthADAPT® is intended for one-time use only.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K071065